CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
22-134

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

18 June 2010

NDA: 22-134

Drug Product Name
Proprietary: (b) (4)
Non-proprietary: alcaftadine ophthalmic solution – 0.25%

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
September 29. 2009	September 29, 2009	October 1, 2009	October 1, 2009

Submission History (for amendments only) – N/A

Applicant/Sponsor
Name: Vistakon Pharmaceuticals, L.L.C.
Address: 7500 Centurion Parkway, Jacksonville, Florida 32256.
Representative: Lorna-Jane Bremer, Director, Global Reg. Affairs
Telephone: (973)-385-0557, Johnson & Johnson Consumer Companies, Inc.

Name of Reviewer: Vinayak B. Pawar, Ph.D.

Conclusion: The application is recommended for approval from Product Quality Microbiology standpoint.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUBMISSION PROVIDES FOR: A new drug application for the treatment of allergic conjunctivitis.

3. MANUFACTURING SITE: (b) (4)

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: A few drops of 0.25% ophthalmic solution for topical application.

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: Treatment of itching associated with allergic conjunctivitis.

B. SUPPORTING/RELATED DOCUMENTS: None

C. REMARKS: An original NDA 22-134 application for (b) (4)™ 0.25%, indicated for the prevention of itching associated with allergic conjunctivitis. This is an electronic submission in a CTDQ format with a PDUFA date on July 29, 2010. IQA was filed by Linda NG on November 11, 2009.

filename: N022134R1

Executive Summary

I. Recommendations

A. Recommendation on Approvability – Recommended for approval.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The manufacturing process consists of (b) (4)

B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _____

Vinayak. B. Pawar, Ph.D.
Primary reviewer, CDER/OPS/NDMS

B. Endorsement Block _____

Stephen Langille, Ph.D.
Secondary concurrence, CDER/OPS/NDMS

C. CC Block
N/A

14 pp withheld in full immediately following this page as (b)(4) CCI/TS.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22134	ORIG-1	VISTAKON PHARMACEUTICALS LLC	ALCAFTADINE OPHTHALMIC SOLUTION O.25%

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/s/

VINAYAK B PAWAR
06/22/2010

STEPHEN E LANGILLE
06/22/2010

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 22-134 **Applicant:** Vistakon Pharmaceuticals, LLC. **Letter Date:** September 29, 2009

Drug Name: (b) (4)™ **NDA Type:** Original **Stamp Date:** August 12, 2009

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	x		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	x		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	x		
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		x	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	x		
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	x		
7	Has the applicant submitted the results of analytical method verification studies?	x		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?		x	
9	Is this NDA fileable? If not, then describe why.	x		

Additional Comments:
The subject drug product is a sterile ophthalmic solution containing 2.5 mg/mL Alcaftadine preserved with Benzalkonium Chloride 50% solution (0.1 mg/mL) and (b) (4) filled. The primary packaging components consisting of a low-density polyethylene (LDPE) bottle, dropper tip, and a polypropylene cap are sterilized (b) (4) The filling equipment which comes in product contact is sterilized by (b) (4) The submission appears to be adequate for Product Quality Microbiology review. No endotoxin specifications were provided for this topical ophthalmic solution.

Reviewing Microbiologist Date

Microbiology Secondary Reviewer/Team Leader Date

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/s/

VINAYAK B PAWAR
10/28/2009

STEPHEN E LANGILLE
10/29/2009

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